

**Amendments to the Claims:**

This listing of claims will replace all prior versions, and listings of claims in the application:

**Listing of Claims:**

1. (currently amended) A method for treatment of a patient, the method comprising:  
  
    providing a vascular prosthesis comprising a stent structure, at least one source of at least one therapeutic capable agent associated with the structure, and a rate-controlling element covering at least a portion of the source;  
  
    implanting the vascular prosthesis within the patient's vasculature including a susceptible tissue site; and  
  
    releasing the at least one therapeutic capable agent into the tissue site so as to inhibit restenosis, wherein the at least one therapeutic capable agent comprises pimecrolimus and wherein the release rate of the pimecrolimus is controlled by the rate controlling element.
2. (previously presented) The method of Claim 1, wherein releasing comprises releasing at least one other compound prior to, concurrent with, or subsequent to the release of the at least one therapeutic capable agent, the other compound being selected from the group consisting of immunosuppressants, anti-inflammatories, anti-proliferatives, anti-migratory agents, anti-fibrotic agents, proapoptotics, vasodilators, calcium channel blockers, anti-neoplastics, anti-cancer agents, antibodies, anti-thrombotic agents, anti-platelet agents, IIb/IIIa agents, antiviral agents, MTOR (mammalian target of rapamycin) inhibitors, non-immunosuppressant agents, tyrosine kinase inhibitors, EGFR/ErbB2 inhibitors, VEGF receptor inhibitors, VEGFR/FGFR/PDGFR inhibitors, NGF receptor inhibitors, anti-EGF receptor MABs, anti-ErbB2 MABs, CDK inhibitors, bisphosphonates, NF-  $\kappa$ B Decoy Oligo, proteins, oligomers, amino acids, peptides, genes, growth factors, anti-sense, and combinations thereof.

Claim 3. (canceled).

4. (original) The method of Claim 1, wherein the at least one therapeutic capable agent includes an active compound, a pro-drug of the active compound, a metabolite of the active compound, a derivative of the active compound, an analogue of the active compound, or a combination thereof.

5. (previously presented) The method of Claim 1, wherein the at least one therapeutic capable agent is released within a time period from about the first day to about 200th day from the implanting of the prosthesis.

6. (original) The method of Claim 1, wherein the at least one therapeutic capable agent is released at a total amount ranging from about 0.1  $\mu\text{g}$  to about 10 g.

7. (original) The method of Claim 1, wherein the at least one therapeutic capable agent is released at a rate between about 0.001  $\mu\text{g/day}$  to about 500  $\mu\text{g/day}$ .

Claims 8.-11. (canceled).

12. (original) The method of Claim 1, wherein releasing comprises releasing the at least one therapeutic capable agent to the susceptible tissue site to effectuate a mammalian tissue concentration ranging from about 0.15 ng of therapeutic capable agent / mg of tissue to about 3 ng of therapeutic capable agent / mg of tissue.

Claim 13. (canceled).

14. (original) The method of Claim 1, wherein releasing comprises releasing the at least one therapeutic capable agent to the susceptible tissue site to effectuate an unwanted metabolite of the therapeutic capable agent having a mammalian tissue concentration of less than 2.5 ng/ mg of tissue.

Claims 15.-19. (canceled).

20. (currently amended) A stent device for intracorporeal use, the stent device comprising:

an expandable stent structure;  
at least one source of at least one therapeutic capable agent associated with the structure, wherein the at least one therapeutic capable agent comprises pimecrolimus; and  
a rate-controlling element disposed adjacent to at least a portion of the source, wherein the therapeutic capable agent is released within a patient's body at a rate determined by the rate-controlling element so as to inhibit restenosis.

21. (original) The device of Claim 20, wherein the expandable structure has a luminal facing surface and a tissue facing surface.

22. (original) The device of Claim 21, wherein the at least one therapeutic capable agent is associated with the expandable structure only on one of the luminal and tissue facing surfaces.

23. (original) The device of Claim 21, wherein the at least one therapeutic capable agent is associated with the expandable structure on the tissue facing surface.

Claim 24. (canceled).

25. (original) The device of Claim 21, wherein the at least one source is disposed adjacent at least one of the luminal or tissue facing surfaces of the expandable structure.

Claims 26.-27. (canceled).

28. (original) The method of Claim 1, wherein the device is configured to deliver the at least one therapeutic capable agent at a phase to a susceptible tissue site of a mammalian intracorporeal body to effectuate a mammalian tissue concentration ranging from about 0.001 ng of therapeutic capable agent / mg of tissue to about 100 µg of therapeutic capable agent / mg of tissue.

Claims 29.-36. (canceled).

37. (previously presented) The device of Claim 20, wherein the device is configured to release at least one other compound prior to, concurrent with, or subsequent to the release of the at least one therapeutic capable agent, the other compound being selected from the group consisting of immunosuppressants, anti-inflammatories, anti-proliferatives, anti-migratory agents, anti-fibrotic agents, proapoptotics, vasodilators, calcium channel blockers, anti-neoplastics, anti-cancer agents, antibodies, anti-thrombotic agents, anti-platelet agents, IIb/IIIa agents, antiviral agents, MTOR (mammalian target of rapamycin) inhibitors, non-immunosuppressant agents, tyrosine kinase inhibitors, EGFR/ErbB2 inhibitors, VEGF receptor inhibitors, VEGFR/FGFR/PDGFR inhibitors, NGF receptor inhibitors, anti-EGF receptor MABs, anti-ErbB2 MABs, CDK inhibitors, bisphosphonates, NF- $\kappa$ B Decoy Oligo, proteins, oligomers, amino acids, peptides, genes, growth factors, anti-sense, and a combination thereof.

Claim 38. (canceled).

39. (previously presented) The method of Claim 1, wherein releasing comprises releasing the at least one therapeutic capable at a release rate so as to provide a sustainable level of therapeutic capable agent to a susceptible tissue site.

40. (previously presented) The method of Claim 39, wherein the release rate is substantially constant, decreasing over time, increasing over time, or substantially non-releasing.

41. (previously presented) The method of Claim 1, wherein releasing comprises releasing the at least one therapeutic capable agent at an initial phase having an initial rate of release ranging from about 0 to about 99% of a subsequent rate of release of a subsequent phase.

42. (previously presented) The method of Claim 1, wherein releasing comprises releasing the at least one therapeutic capable agent at an initial phase having an initial rate of release ranging from about 0 to about 50  $\mu$ g/day, and a subsequent phase having a subsequent rate of release ranging from about 0.01  $\mu$ g/day to about 200  $\mu$ g/day.

43. (previously presented) The method of Claim 1, wherein releasing comprises releasing the at least one therapeutic capable agent at an initial phase having an initial rate of release ranging from about 10  $\mu\text{g/day}$  to about 300  $\mu\text{g/day}$ , and a subsequent phase having a subsequent rate of release ranging from about 0.1  $\mu\text{g/day}$  to about 100  $\mu\text{g/day}$ .

44. (previously presented) The method of Claim 1, wherein releasing comprises releasing the at least one therapeutic capable agent at an initial phase having a time duration of less than about 24 weeks.

45. (previously presented) The method of Claim 1, wherein releasing comprises releasing the at least one therapeutic capable agent at a subsequent phase having a time duration in a range from about 1 hour to about 50 weeks.

46. (previously presented) The method of Claim 1, wherein releasing comprises releasing the at least one therapeutic capable agent at a substantially constant rate ranging from about 0.01  $\mu\text{g/day}$  to about 200  $\mu\text{g/day}$ .

47. (previously presented) The method of Claim 1, wherein releasing further comprises delaying release of the therapeutic capable agent, wherein the delay is sufficiently long to allow formation of a sufficient amount of cellularization, endothelialization, or fibrin deposition at a susceptible tissue site or on the device.

48. (previously presented) The device of claim 20, wherein the source is associated with the expandable structure by coating, spraying, dipping, vapor deposition, plasma deposition, or painting of the source onto or in the expandable structure.

49. (previously presented) The device of Claim 20, wherein at least a portion of the rate-controlling element forms a matrix with the therapeutic capable agent.

50. (previously presented) The device of Claim 20, wherein the therapeutic capable agent is released by surface degradation, bulk degradation, diffusion, or hydrolysis of the rate-controlling element.

51. (previously presented) The device of Claim 20, wherein the rate-controlling element is formed from a material selected from the group consisting of parylene, parylast, polyurethane, polyethylenes imine, cellulose acetate butyrate, ethylene vinyl alcohol copolymer, silicone, polytetrafluorethylene (PTFE), poly (methyl methacrylate butyrate), poly-N-butyl methacrylate, poly (methyl methacrylate), poly 2-hydroxy ethyl methacrylate, poly ethylene glycol methacrylates, poly vinyl chloride, poly(dimethyl siloxane), poly(tetrafluoroethylene), poly (ethylene oxide), poly ethylene vinyl acetate, poly carbonate, poly acrylamide gels, N vinyl-2-pyrrolidone, maleic anhydride, Nylon, cellulose acetate butyrate (CAB), mixtures, copolymers, and combinations thereof.

52. (previously presented) The device of Claim 20, wherein the rate-controlling element comprises a non-porous material.

53. (previously presented) The device of Claim 20, wherein the rate-controlling element comprises parylene.

54. (previously presented) The device of Claim 20, wherein the rate-controlling element has thickness ranging from about 10 nm to about 100  $\mu\text{m}$ .